Available online at www.sciencedirect.com

SciVerse ScienceDirect

Procedia Computer Science 16 (2013) 581 – 590

Procedia Computer Science

Conference on Systems Engineering Research (CSER'13)
Eds.: C.J.J. Paredis, C. Bishop, D. Bodner, Georgia Institute of Technology, Atlanta, GA, March 19-22, 2013.

# User-centred system design approach applied on a robotic flexible endoscope

Jeroen G. Ruiter[a,b,*], Mascha C. van der Voort[b], G. Maarten Bonnema[b]

[a]*DEMCON advanced mechatronics, Zutphenstraat 25, 7575 EJ Oldenzaal, The Netherlands*
[b]*University of Twente, P.O.Box 217, 7500 AE Enschede, The Netherlands*

**Abstract**

Complex systems, like surgical robots, are designed by engineers. It is very difficult for them to determine the different needs and desires of all stakeholders. Especially when designed from scratch, end user input is essential in creating a system that has added value, is user friendly, and can be easily integrated into practice. For the development of a robotic flexible endoscope we have involved physicians, nurses, and equipment suppliers in our design approach. Seven steps are executed to convert user preferences and capabilities into concepts:

- Determine *focus area* of development.
- Create the *current workflow* of system application to understand (the context of) use.
- Determine *problem definition and design goal.*
- Create the *future workflow*, in which current problems are eliminated and major system wishes are fulfilled.
- Translate the future workflow into a *functional overview* that contains system functions.
- Select and configure the appropriate construction elements into *physical overviews*, being preliminary concepts.
- Decompose physical overview into *manageable modules*.

These views are evaluated by the major stakeholders and together form a system architecture. The system architecture helped us in defining the robotic modules required to fulfill all stakeholders' needs and desires. Demonstrators were built to evaluate critical concepts in clinical relevant experiments.



Keywords: system design methodology; user-centred design; usability; application; surgical robotics

## 1. Introduction

Torry-Smith et al. [1] argue that the most commonly reported sets of challenges in system design are primarily related to the way a system concept can be described and how information linked to the system concept can be shared across engineering disciplines. However, in system development processes not only engineers but many more

* Jeroen Ruiter. Tel.: +31-6-250-278-06
*E-mail address*: j.g.ruiter@utwente.nl


doi:10.1016/j.procs.2013.01.061

stakeholders are involved. Especially in systems with critical user interaction the intended end user should be part of the system design process to ensure that the system will function satisfactory in different use situations [2].

As mentioned in [3] the availability of *system design* methods is minimal. Central issue is how can designers from different disciplines work together effectively, how can the problem of designing a large and complex system be divided into smaller, more manageable parts, and how can the fit between these parts that are designed by multidisciplinary teams be guaranteed. This is what system architecting is about [3]. Maier and Rechtin [4] also address needs, worries, and complications, originating from human and business aspects. They see the system designer as an “agent of the client”. What is missing in their work is a stepwise approach in acquiring user information.

*Product development* methodologies are often constrained to a specific discipline. In industrial design a wide variety of user-centred product development methods are available. Although used terminology and phase arrangement might differ, most methods prescribe similar activities. The methods are developed to be generic and only give guidance with respect to the main process steps. It is up to the product development team to adapt the method to the specific project [5]. The concept of user-centred design was originally introduced by Norman and Draper [6] and applied on human-computer interaction design. Gulliksen et al. [7] have composed an overview of 12 key principles to involve end users in human-computer interaction development processes. Those principles are also very well applicable in hardware design.

In this paper we discuss our user-centred system design approach for designing complex systems with critical use aspects. In our method we integrate the discipline of system architecting in system design with the discipline of incorporating human aspects in product design. It is not derived from one of the known methodologies, but based on twelve years of design experience of the first author, user-centred design approaches developed by the second author, and system architecting methods of the third author. Creation of our methodology was not a goal on itself, but the result of the Teleflex research project in which a robotic flexible endoscope for surgery is developed. Our methodology can be an inspiration for similar system development processes. Since physicians have very strong expectations about usability, this approach can also be used when designing other (non-medical) complex systems in which user interaction is critical. There is no scientific way for verifying that our approach is best, but the final system is very much appreciated by participants in usability experiments. Additionally, equipment suppliers have shown their interest in commercializing our product ideas.

In this paper the application of our methodology is shown. To share our practical experience, we use the Teleflex project to discuss the various steps. This paper is structured as follows: In Section 2 the Teleflex project is introduced. In Section 3 the creation of an system architecture is shown. Finally Section 4 contains the discussion.

## 2. Teleflex case

The Teleflex project targets the research, design and construction of a robotic system that supports physicians in performing flexible endoscopy. In flexible endoscopy the interior surfaces of the gastrointestinal, reproductive and respiratory tracts are diagnosed and treated. The physician uses a flexible shaft with a camera at the steerable distal tip that is introduced in the natural body openings. Instruments for therapy can be inserted in the endoscope. In Fig. 1 both use cases, diagnosis and therapy, are depicted.

Fig. 1. Flexible endoscopy (a) diagnosis; (b) therapy

At present there are no flexible endoscopes available that can be controlled in an intuitive and user-friendly way by one person. Main usability problems are related to the control section of the flexible endoscope. Additionally, flexible endoscopes and its instruments have limited capacity to execute procedures that require advanced maneuverability. Robotic technology has the potential to improve current practice and to perform advanced interventions easily, safely, and solely. The aim is to decouple user interface and surgical end effector mechanically, enabling the use of computer techniques to enhance the capabilities of the physician and to use the full potential of flexible instruments. Apart from improving current flexible endoscopy, this will cause a shift of more invasive surgical procedures that require external incisions to endoluminal procedures in the gastrointestinal, reproductive and respiratory tracts that use the natural body openings (mouth, anus, ureter, or vagina) as access point, as shown in Fig. 2a.

Since a decade several research groups focus on transluminal procedures in which the natural orifices provide the entry point as well, see Fig. 2b. The internal membrane of the digestive tract or vagina is perforated to reach the abdominal cavity, thereby avoiding external abdominal wall incisions. This surgical approach is also known as Natural Orifice Transluminal Endoscopic Surgery (NOTES) and performed in experimental interventions. Instrument control and sterility issues are even more critical than in endoluminal procedures.

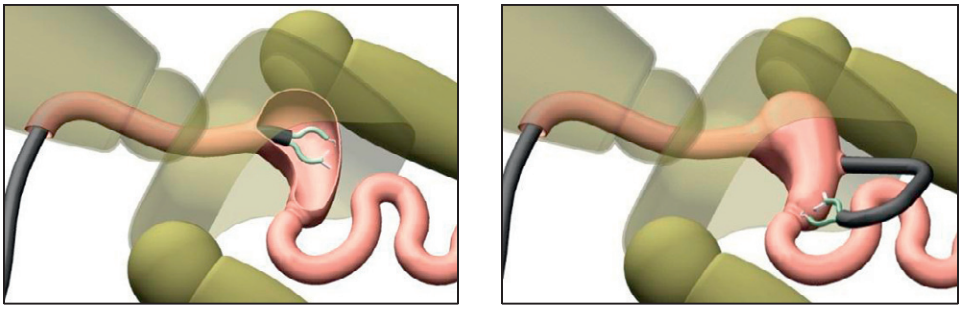

Fig. 2. Flexible endoscopy (a) endoluminal; (b) transluminal

## 3. System architecture creation

A system architecture defines the parts constituting a system and allocates the system's functionality and performance over its parts, its user, its super system and the environment in order to meet system requirements [3]. Interviews, observations and a literature study are a good start to obtain relevant design information. Unfortunately, interpretation and translation into a list of requirements always leads to loss of information [2]. Designers should not only rely on their own experience and common sense but have to verify requirements and ideas with end users. For that reason recording design information into overviews, that together form a system architecture, helps to facilitate a joint understanding among all stakeholders in a design process. Good system architectures have several different overviews [1], [8]. Design information should be represented in an easily understandable format to include non-experts into the design process. For a robotic flexible endoscope this means that engineers should understand the medical context and physicians the technical opportunities (limitations). If a system architecture is easily accessible for stakeholders with different backgrounds, verification of design information is a team process. A common pitfall of architecture overviews is a high degree of too abstract and too academic statements [9]. The adage "A picture is worth a thousand words" should be kept in mind when creating a system architecture.

The next sub-sections describe the steps that need to be executed to create an system architecture according to our method.

### *3.1. Step 1 - Focus development*

In the past often technology was the limiting factor in system development. Currently with the integration of mechanics, electronics and software we can create nearly anything. Insufficient focus could result in a system that does not comply with stakeholders expectations and will not be adopted. Common mistakes are for instance that a system cannot be easily integrated into practice, is ahead of its time, or is too complex. Designers should verify if their interpretation of the initial assignment matches with end users demands. At least end users should be interviewed about what they expect from the system under development. The essence of the objectives of the customers can be captured in terms of key drivers. The key drivers provide direction to capture detailed requirements and to focus the development [10]. For the Teleflex project a user group of medical specialists in general surgery, cardiothoracic surgery, urology, and gastrointestinal endoscopy is formed. From interviews and attending clinical interventions the design team composed the following key drivers:

- Intuitive and user friendly control.
- Single person control.
- Backwards compatibility with existing gastro- and colonoscopes.

Our motivation for adding the first two key drivers is discussed in Section 2. The last key driver is added to prevent that stakeholders are confronted with high costs related to replacement of endoscopic equipment. Additionally, in this way current endoscope qualities, like cleanability and good image quality, are maintained. Connection of the robotic system to the endoscope does not demand any adaptations of the endoscope.

Our contact with the user group was also used to gain insight into the possible applications of the future system, and the associated functional and technical requirements from a medical perspective. A provisional list of in total 18 endoluminal and transluminal procedures was composed that could benefit from robotic control of a flexible endoscope. To get focus, we subsequently asked the user group to fill in a selection matrix that connects possible procedures to selection criteria that are formulated by the Teleflex team. The selection criteria incorporate medical as well as commercial values, like:

- Robotic surgery leads to less intra- and postoperative pain and/or scars.
- Number of hospitals that perform the procedure.

The scores of the selection matrix and the findings collected during the interviews and observations were discussed during a plenary meeting with the user group of medical experts, Teleflex PhD’s (industrial design, mechatronics, and control engineering) and their supervisors. In this meeting it was concluded that Teleflex should focus on endoluminal interventions that require advanced manipulation in a limited space, like organ-sparing endoscopic removal of benign and early malignant lesions in the gastrointestinal tract (mucosectomy). However, we agreed also to keep the door open to simpler (e.g. biopsy and polypectomy) as well as more complex transluminal (e.g. cholecystectomy) procedures. This last addition shows that getting focus in an early stage of a development process is difficult. During system development the picture of the intended design goal will become sharper and for that reason a system architecture should be a ‘living’ document that can be easily adapted to new insights that appear [11].

### *3.2. Step 2 - Create workflow of current system application*

An accurate, comprehensive insight into how a system is used in practice by its users and the context in which system use takes place is essential for designing systems that meet user expectations. To be able to identify problems related to current practice, the designer first summarizes obtained design information into a workflow that describes the current way of system use. In Fig. 3, for illustration purposes only, part of the workflow is shown for performing endoscopic submucosal dissection, being one of the most demanding therapeutic endoluminal procedures performed in the clinic. The required functionality of the robotic endoscope to perform this procedure is a good starting point for a more generic system to perform advanced endoluminal procedures, being our focus area of development.

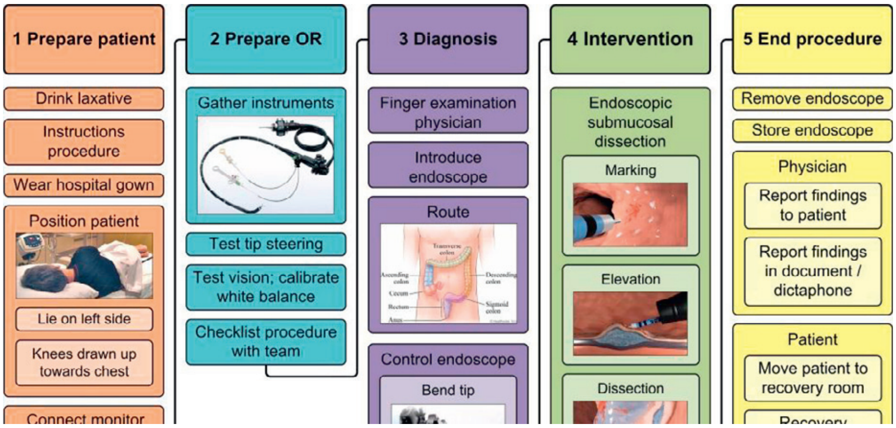


Fig. 3. Current workflow

### *3.3. Step 3 - Determine problem definition and design goal*

Setting up the current workflow, as described in the previous section, helps to determine a problem definition and to set a common design goal for the system under development. Creating the workflow enforces the designers to critically look at all steps involved in the use of a system and to reveal problems.

What became clear form analyzing, documenting, and reviewing the current workflow of flexible endoscopy is that physicians are not completely in control while interacting with patients. At present there are no flexible endoscopes available that can be controlled in an intuitive, ergonomic, and user-friendly way by one person. Assistants are required to control part of the motions or degrees of freedom (DOFs) of an endoscope and its instruments according to spoken instructions. As a consequence the physician is missing valuable force feedback information on tissue interaction, and in addition communication errors easily occur.

Despite the fact that current endoscopes and their instruments are already difficult to steer, flexible endoscopic multitasking systems are currently developed with additional DOFs, see Fig. 4. The platform used is comparable to the flexible shaft of traditional flexible endoscopes and contains the same steering concepts. The instruments that can be inserted in the endoscope have additional degrees of freedom. Besides axial translation and rotation, the tip of these instrument can bent to allow movements in three-dimensional space. These endoscopic systems mostly target on transluminal procedures, but could also be beneficial for endoluminal interventions that require advanced manipulation in a limited space. Currently they are not suitable yet for single person operation and require at least two experienced physicians that cooperate closely. The technology is up to now only used in experimental interventions.

Fig. 4. Flexible endoscopic multitasking platform

The future of natural orifice surgery (endoluminal as well as transluminal) lies in the application of computer and robotic technologies to support the physician [12]. Clinical procedures should become less dependent on the skills of users in handling the required instruments. The robotic concepts of Teleflex are based on remote controlled electro-mechanical steering of the endoscope. Key factor is that user interface and tools are mechanically decoupled, as known from telemanipulation systems. The physician uses a master console (user interface) to control a slave robot (actuated tools) positioned near the patient. The user interface is optimized for the physician and the tools are optimized for the intervention.

Fig. 5 shows a possible configuration for a master-slave set-up for telemanipulated surgery with flexible instruments. A split system is not essential, but could help to solve for instance space or sterility issues. Teleflex focuses on ultimately introducing a teleoperated robotic system into clinical practice that allows a single physician to perform complex endoluminal and possibly transluminal procedures.

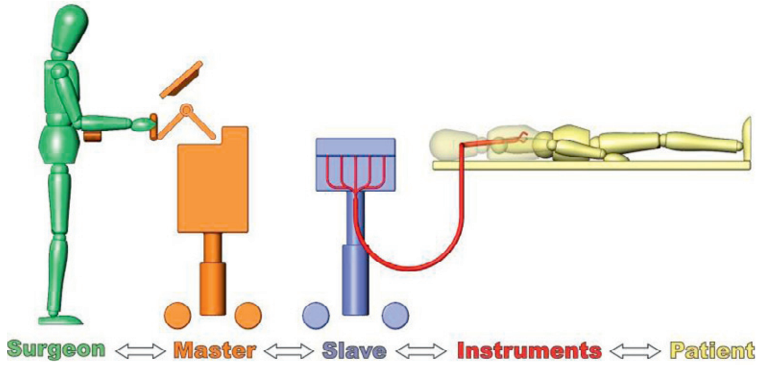


Fig. 5. Telemanipulation with flexible instruments; the Teleflex system structure

### 3.4. Step 4 - Create workflow of future system application

The next step is to translate the current workflow into the future workflow using the basic structure shown in Fig. 3. In the future workflow current problems are eliminated and major product wishes are fulfilled. It is a high level description of personnel and procedural steps involved. The future workflow helps to understand the context of use and shows critical design aspects.

Fig. 6 shows an example of part of the future workflow for a telemanipulated endoluminal surgical procedure using an endoscopic multitasking system. Robotic modules are implemented, while taking account of the overall clinical workflow in the hospital. Some preliminary concepts already appear when creating the future workflow. These concepts contain important Teleflex key drivers like single person control and backwards compatibility of the system with existing endoscopes.

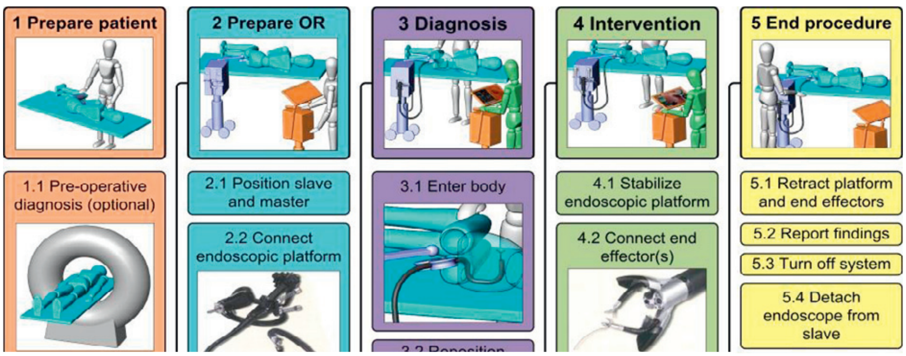


Fig. 6. Future workflow

### 3.5. Step 5 - Create functional overview

A functional overview shows how the general goal of a system is achieved by the realization of functions. This decomposition into functions and sub functions is useful for managing complex systems.

As shown in Fig. 7, for building a functional overview the workflow of future system application is a suitable starting point.

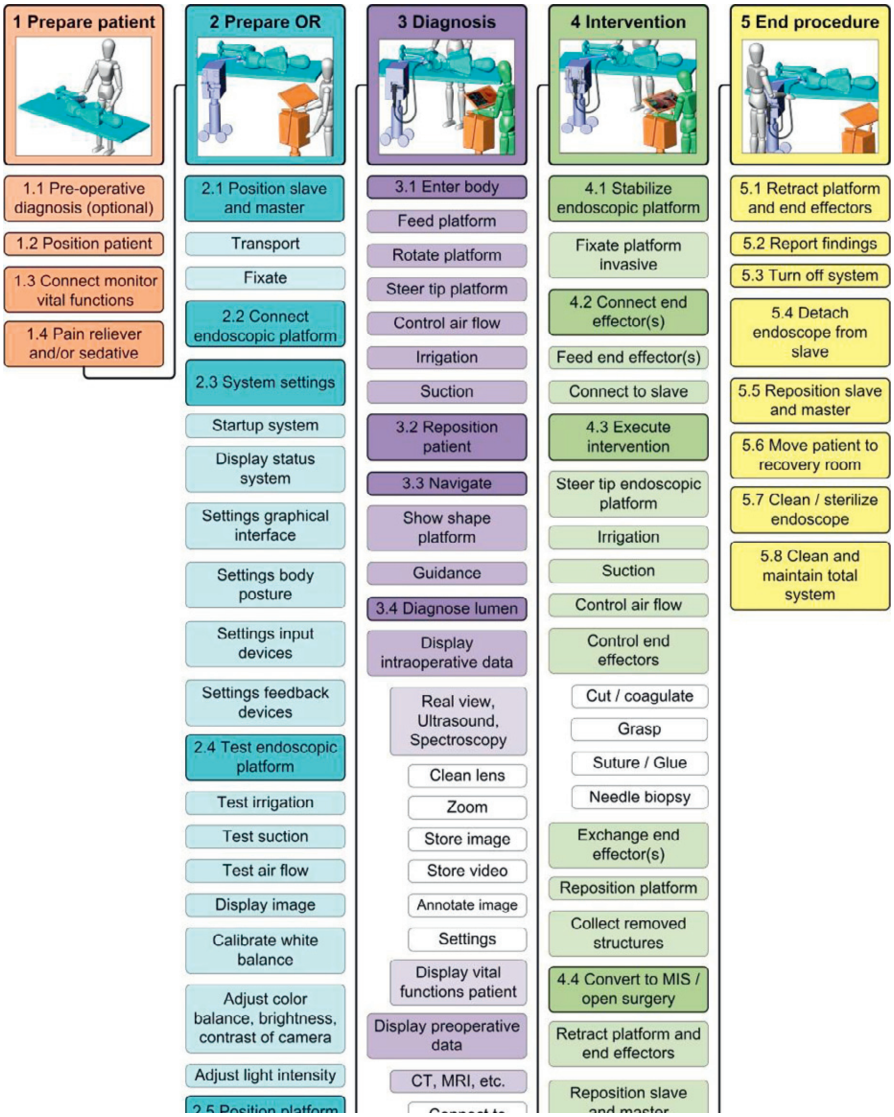


Fig. 7. Functional overview

The functional overview gives a high level description of functions. A system requirements document that contains detailed functional and technical requirements is needed for engineers to design the final system. The functional requirements provide detailed information about the context of use. A typical functional requirement for a user interface for telemanipulated surgery with flexible instruments is: "Input controller is able to eliminate hand tremor". In the technical requirements the functional requirements are specified and quantified, for example: "Input controller algorithm filters human hand tremor frequencies of 10 to 100 Hz with amplitudes of 0 mm to 2 mm".

### *3.6. Step 6 - Create physical overview*

In this section the transition of a functional overview into a physical overview is discussed. A physical overview (or scheme) is an outline solution to a design problem, carried to the point where the means of performing each major function has been fixed, as have the spatial and structural relationships of the principal components [3]. Several physical overviews could be created to visualize different thoughts of the envisioned system. These have to comply to the functional and technical requirements and should be evaluated with end users. Four to six concepts are feasible; they can be made sufficiently different and they can be worked out far enough without wasting too much effort [3]. In Fig. 8a an example is given of a physical overview. Additionally, concept choices are documented in a concept design description, a reference document that secures the argumentation for choosing specific physical components, their functions and their relations.

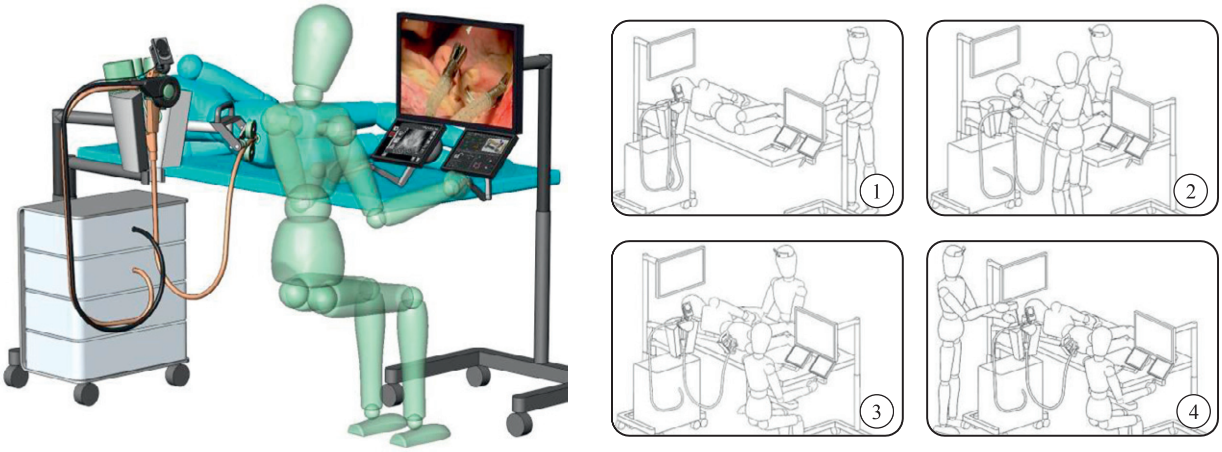


Fig. 8. (a) Physical overview (b) Updated future workflow

During the design process knowledge of the system will evolve, as a consequence the components of the system architecture will evolve too. The physical overviews can for instance be used to update the future workflow, as shown in Fig. 8b. It is an opportunity to present stakeholders a sharper picture of the intended design goal. It is a good way to verify if the design process is still on the right track.

### *3.7. Step 7 - Decompose physical overview into manageable modules*

Up to now the system is considered as being an integrated solution. There are an enormous number of items to consider. The only way to create these systems is to divide and rule. The determination of the division-lines is what system architecting is about. However, how the decomposition from system level to module level is created is difficult [3].

Besides the described benefits for development, decomposition of the system into manageable parts is also beneficial for the end user. Modularity of the Teleflex system allows end users to customize the robotic endoscope to their clinical requirements. In Teleflex add-on robotic modules are positioned on traditional endoscopes. The physician uses a remote control to actuate the degrees of freedom of the endoscope and its instruments. For diagnostic procedures it suffices to only use a steering module that improves the intuitiveness of navigating the endoscope through the digestive tract. For therapeutic procedures additional modules can be integrated that allow a single user to control flexible endoscopic multitasking systems. In total three robotic modules are defined:

- Robotic steering module - Diagnostic procedures

The control section of a traditional endoscope is not ergonomic, user friendly and intuitive in use. In the robotic module the current controls (navigation wheels and buttons) are actuated by motors combined in a drive unit. With a dedicated remote control the deflection of the tip, insufflation, rinsing, suction and the programmable switches (e.g. photo, video, narrow band imaging) are controlled singlehandedly by the physician, while the other hand manipulates the shaft of the endoscope, as shown in Fig. 9a.

- Robotic shaft manipulation module - Existing and upcoming therapeutic procedures

With the addition of instruments in therapeutics, single person control can only be obtained if the flexible endoscope can be operated with one hand and instruments with the other. The robotic steering module is combined with a robotic module that actuates the shaft of the flexible endoscope. The physician uses one multi-degrees-of-freedom (multi-DOF) input controller to steer, advance, rotate, and maintain the position of the motorized flexible endoscope, while the other hand is able to manipulate instruments, as shown in Fig. 9b.

- Robotic instrument manipulation module - Future (long-term) therapeutic procedures

The instrument manipulation module is used to control the motions of advanced endoscopic instruments with multiple degrees of freedom. These instruments should allow complex actions like suturing to be performed. It is noted that such instruments are not commercially available yet and as such this module is the most experimental. Given the high number of degrees of freedom the physician has to manage an optimized working console is designed providing a comfortable working posture, structured data presentation, and dexterous input devices. The complete setup is shown in Fig. 9c.

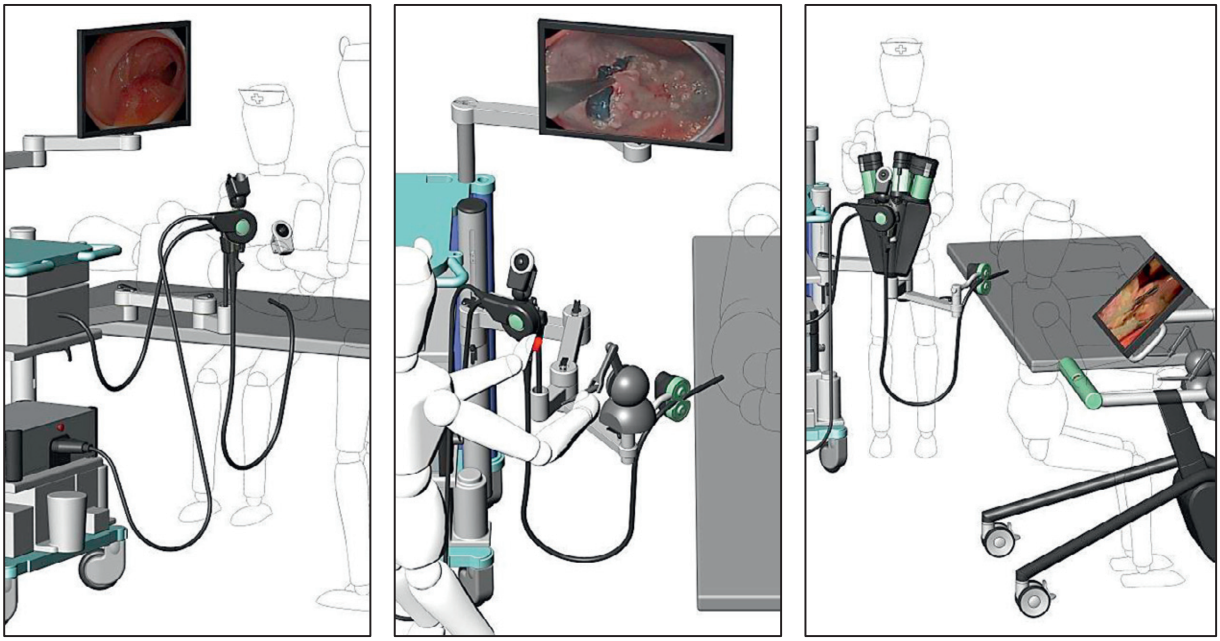

Fig. 9. Robotic modules (a) steering; (b) shaft manipulation; (c) instrument manipulation

The physical realization and testing of the first and second robotic module are discussed in [13] and [14]. The third module is under construction and will be discussed in a future paper.

The fit between the separate modules, both in geometry and functionality has to be checked constantly during the development process. Finally all modules have to come together during the integration step that will also be discussed in a future paper.

### *3.8. Evaluation of the system architecture*

The overviews created in the previous seven steps are together a system architecture. Our system architecture was evaluated during its creation. From the start clinical personnel was involved in verifying our ideas about how a robotic flexible endoscope should be fitted into clinical practice. In a later stage, when our ideas became more concrete and were visualized into concepts, system suppliers were asked to judge its feasibility. Because the concepts were presented in an easily understandable format, mostly rendered 3D views, we could in an early stage convince commercial partners of the added value of our robotic flexible endoscope. They are now partners in the Teleflex project and provide valuable feedback.

## 4. Discussion

In this paper we discussed our user-centred system design approach for designing complex systems in which user interaction is critical. We showed the creation of a system architecture for the Teleflex project. The aim of the Teleflex research project is to develop new technologies that will facilitate endoscopic procedures. We designed a robotic endoscope that solves the most important user interface problems currently faced in flexible endoscopy. Three robotic modules are (being) defined, designed, build, tested and discussed in publications. The final integrated Teleflex system is a generic tool suitable for diverse interventions and should ultimately bring high volume natural orifice surgery (endoluminal as well as transluminal) into the clinic.

Seven steps were executed to convert user preferences and capabilities into a system architecture: (1) determining the focus area, (2) analysing the current workflow, (3) problem and design goal definition, (4) creating the future workflow, (5) translating the future workflow into a functional overview (6), selecting and configuring appropriate construction elements into physical overviews, and (7) decomposing the physical overview into manageable modules. Our method is mainly based on visualizing ideas and verifying these overviews with stakeholders. This implicates that the design team should have the skills (and tools) to be able to put ideas clearly on paper. An industrial design engineer is very well capable of doing this and should be part of the design team. Additionally, industrial design engineers are educated to think about the human factors in the design process. This is of course very important in systems with critical use aspects.

Because of its exploring character similar commercial projects are often split in a proof-of-principle, prototype, and pre-production phase. This research projects limits itself to the proof-of-principle phase. Demonstrators were built to test the feasibility of critical functions, evaluate the concepts in clinical relevant experiments and to interest commercial partners. Next step is to bring the project into the realization phase. Our methodology supports in translating an abstract design assignment into a concrete concept proposal. However a project does not stop in the conceptual phase. The realization phase also requires a structured approach, in which our methodology does not yet provide. Future research should focus on expanding our methodology to cover the complete design process.

There is no scientific way for verifying that our approach is best, but the feedback we got on our demonstrators indicate that we managed to include the interests of all stakeholders. Our methodology can similarly be used when designing other (non-medical) complex systems in which user interaction is critical.

## References

1. J.M. Torry-Smith et al., Mechatronic Design – Still a Considerable Challenge. In Proceedings of International Design Engineering Technical Conferences & Computers and Information in Engineering Conference, Washington, USA, 2011.

2. M.C. van der Voort and M. Tideman, Combining Scenarios and Virtual Reality into a New Approach to Including Users in Product Design Processes. In Journal of Design Research, Volume 7, No.4, pp. 393-410, 2008.

3. G.M. Bonnema, FunKey Architecting - an Integrated Approach to System Architecting Using Functions, Key Drivers and System Budgets. Ph.D. Thesis, University of Twente, Enschede, The Netherlands, 2008.

4. M.W. Maier and E. Rechtin, The Art of Systems Architecting. Second Edition, CRC Press, Boca Raton, Florida, 2000.

5. F. Hoolhorst, Structuring User-Centred Product Development Processes. Ph.D. thesis, University of Twente, The Netherlands, 2012.

6. D.A. Norman and S.W. Draper, User Centered System Design. Lawrence Erlbaum Associates, Hillsdale, New Jersey, 1986.

7. J. Gulliksen et al., Key Principles for User-Centred Systems Design. Behaviour & Information Technology , Vol . 22, No. 6, 2003.

8. ISO/IEC/IEEE 42010: 2011, Systems and software engineering - Architecture description.

9. G.J. Muller, How to Create an Architecture Overview. http://www.gaudisite.nl/OverviewHowToPaper.pdf, accessed on Sep. 28, 2012.

10. G.J. Muller, CAFCR: A multi-view method for embedded systems architecting: Balancing genericity and specificity. Ph.D. thesis, Delft University of Technology, The Netherlands, 2004.

11. P.D. Borches and G.M. Bonnema, 'Living' Architecture Overviews - Supporting the Design of Evolutionary Complex Systems. In Proceedings of the CIRP Design Conference, Enschede, the Netherlands, 2008.

12. J. Marescaux et al., Surgery Without Scars. In Archives of Surgery, Vol. 142, No. 9, pp. 823-827, 2007.

13. J.G. Ruiter, E.D. Rozeboom, M.C. van der Voort, G.M. Bonnema, I.A.M.J. Broeders, Design and Evaluation of Robotic Steering of a Flexible Endoscope. In Proceedings of International Conference on Biomedical Robotics and Biomechatronics, Rome, 2012.

14. J.G. Ruiter et al., Robotic Control of a Traditional Flexible Endoscope. In Proceedings of Hamlyn Symposium, London, 2012.